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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,140	09/16/2003	Christine Henry	8707-2163	3993
7590	12/27/2005			
Robert M. Isackson Orrick, Herrington & Sutcliffe, LLP 666 Fifth Avenue New York, NY 10103				EXAMINER KRAMER, NICOLE R
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/663,140	HENRY ET AL.
	Examiner Nicole R. Kramer	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9/16/03</u>	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 9/16/2002. It is noted, however, that applicant has not filed a certified copy of the 02-11430 application as required by 35 U.S.C. 119(b).

### ***Information Disclosure Statement***

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Objections***

3. Claim 1 (and all claims depending therefrom) is objected to because of the following informalities: "wherein said antibrodycardia therapy" in claim 1, line 19 should be "wherein said antibradycardia therapy." Appropriate correction is required.

4. Claim 8 is objected to because of the following informalities: Examiner believes that it should depend from claim 7.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,074,308 ("Sholder et al") in view of U.S. Patent No. 5,462,060 ("Jacobson et al.").

Sholder et al. discloses a pacemaker (10) including means for sensing ventricular and atrial cardiac activity (leads 16 and 22 and corresponding sensing amplifiers 18 and 20), means for delivering an antitachycardia therapy able to apply selectively a defibrillation shock, a cardioversion shock and an antitachycardia pacing stimulation (pulse generator and control logic 12), means for detecting patient activity and means for delivering antibradycardia stimulation according to detected patient activity (Sholder et al. discloses that pacemaker 10 may be a rate-responsive pacemaker; see col. 8, lines 20-22. When pacemaker 10 is a rate-responsive pacemaker, it necessarily includes means for detecting patient activity). Sholder discloses means for analyzing the detected cardiac activity with respect to a given threshold frequency of analysis and determining a frequency of cardiac activity (pacemaker 10 determines whether the heart rate exceeds a tachycardia reference rate; see col. 16, lines 23-54). Sholder discloses that the tachycardia reference rate may be less than the maximum tracking rate of the

pacemaker, which Examiner considers to be the maximum frequency stimulation of claim 1 (see, for example, col. 13, line 38 - col. 14, line 3). In response to a detected tachycardia, pacemaker 10 changes the P-V delay and evaluates the resulting cardiac cycle in order to distinguish a natural fast heart rate condition from a pacemaker mediated tachycardia (see, col. 14, lines 39-58 and col. 15, lines 20-40).

Sholder et al. fails to disclose that the pacemaker includes means for discriminating between a ventricular tachycardia and a ventricular fibrillation. Jacobson et al. teaches a pacemaker algorithm for discriminating between a ventricular tachycardia and a ventricular fibrillation (see Fig. 1). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the pacemaker disclosed in Sholder et al. to discriminate between a ventricular tachycardia and a ventricular fibrillation as taught by Jacobsen et al. in order to enable the pacemaker to deliver the most appropriate therapy for a detected, abnormal heart rate.

With respect to claims 2 and 4-5, the pacemaker of Sholder et al. is capable of detecting an occurrence of a ventricular extrasystole via leads 16 and 22 because the pacemaker is continuously detecting cardiac activity.

With respect to claim 3, Jacobsen et al. teaches means for identifying the origin of the cardiac event (see Fig. 1).

With respect to claim 6, Sholder et al. discloses that the pacemaker includes means for detecting a presence of a confirmed rate of ventricular tachycardia (pacemaker 10 determines whether the heart rate exceeds a tachycardia reference rate; see col. 16, lines 23-54).

With respect to claims 7-9, Sholder et al. discloses that in response to a detected tachycardia, pacemaker 10 changes the P-V delay and evaluates the resulting cardiac cycle in order to distinguish a natural fast heart rate condition from a pacemaker mediated tachycardia (see, col. 14, lines 39-58 and col. 15, lines 20-40). The pacemaker is inherently capable of changing the P-V delay to a tachycardia detection time interval increased by a predetermined, programmable safety factor.

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 5,882,352 teaches a rate-responsive antitachycardia pacemaker which utilizes the signal from the activity sensor to adjust the upper limit of a detection rate zone used by the pacemaker to detect when an arrhythmia is present.

U.S. Patent No. 5,458,622 teaches an IMD which distinguishes between pathologic and physiologic tachycardias by the application of predetermined distinction criteria programmed into it.

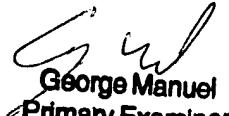
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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12/22/05

  
George Manuel  
Primary Examiner